REMARKS

Claims 1 through 13 remain pending in the present application. The specification has been amended to correct minor informalities. The Examiner has found that the information disclosure statement submitted on April 24, 2006, is in compliance with the provisions of 37 CFR 1.97 and has been considered.

Objection to the Specification

At page 2 of the instant Office Action, the Examiner requests an update of the specification at page 1, line 1, to reflect the priority benefits of the present application. The applicants have reviewed the portion of the specification identified by the Examiner and have amended same to correct minor informalities. However, the applicants respectfully note that the section entitled "Cross Reference to Related Applications", page 1, lines 5-8, presently contains the requested priority data. Likewise, a review of corresponding U.S. Published Application No. 2006/0204490 reveals that the requested priority data with respect to both applicants' PCT application and their U.S. Provisional application is included. Accordingly, applicants request that the Examiner review and confirm that the requested information has already been provided or provide further explanation as to what is required.

Rejection under 35 U.S.C. §102(b) over Reich et al.

Claims 1 through 13 stand rejected under 35 U.S.C. §102(b) as being anticipated by Reich et al. (U.S. Published Application No. 2002/0042378). The Examiner has taken the position that:

> Reich et al teach a hemostatic composition comprising a continuous liquid phase comprising thrombin and solid phase

having polymeric particles and method of making, therefore, Note page 3, [0021], all lines wherein a hemoactive composition is defined as having a liquid and solid phase and the solid phase is comprised by the liquid phase.

Further a biocompatible polymer is disclosed. Also at page 2, [0012], line 9 thrombin is disclosed as the desirable hemostatic agent. Also the irradiation is disclosed as a conventional sterilization procedure, note the last 4 lines of [0012] at page 2. Therefore, the hemostatic and method of making it are clearly disclosed by the cited reference. Each of the proteins [is] disclosed as well. The steps of the process of combining and mixing and [irradiation] are discussed.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings of the cited reference.

Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Nature of the Present Invention

The present invention is directed to a sterile hemostatic composition, comprising: a continuous, biocompatible liquid phase comprising sterile thrombin; and a solid phase comprising particles of a biocompatible polymer suitable for use in hemostasis and which is substantially insoluble in said liquid phase, said continuous liquid phase comprising said solid phase and said sterile thrombin substantially homogenously dispersed there through, wherein the ratio of said liquid phase and said solid phase is effective to provide said composition with hemostatic properties and said sterile thrombin comprises enzymatic activity (Claim 1).

Importantly, the presently claimed compositions are *liquid dispersions*, which contain sterile thrombin in the continuous liquid phase. One benefit of the

presently claimed compositions is their use in providing hemostasis to uneven or hard to reach surfaces – a direct result of their flowability (specification, page 1, lines 18-21). However, unlike the conventional slurries described, the presently claimed compositions contain sterile thrombin in solution.

Reich et al.

Reich et al. disclose dried hemoactive materials comprising a dried, cross-linked biologically compatible polymer which forms a hydrogel when exposed to blood and a non-cross-linked biologically compatible polymer which solubilizes when exposed to blood ([0012], page 1). The Reich et al. materials can be formed into sheets ([0012], page 1), powders, pellets, large blocks, plugs, cylinders, tubes, split tubes, or other forms ([0012], page 2). Reich et al. suggest that a number of hemoactive materials can be incorporated into their compositions, such as thrombin ([0012], page 2). The cross-linked biologically compatible polymer is typically present at levels of 50-95 wt%, preferably 80-95 wt% [0016]. The Reich et al. compositions can be sterilized by conventional methods, such as gamma-irradiation ([0012], page 2).

As may be appreciated from a careful review of Reich et al., Reich et al. fail to disclose or suggest that their compositions can be in the form of a liquid dispersion, as claimed herein.

In this regard, the Examiner directs attention to paragraph [0021] for the proposition that Reich et al. disclose liquid compositions. However, a fair and complete reading of paragraph [0021] reveals that after forming a liquid composition of the dissolved, non-cross-linked polymer and the dispersed cross-linked polymer, Reich et al. *dry the composition to a solid phase form*. Reich et al. never disclose sterilization of the liquid, intermediate composition; as such, *the intermediate composition cannot comprise sterile thrombin*, as claimed

herein. Notably, Reich et al. exemplify sterilization of solid form materials containing thrombin ([0049].

As stated in MPEP §2131, in order to constitute anticipation under the law, a patent or publication must contain within its four corners a sufficient description to enable the person of ordinary skill to make the invention without undue experimentation. All material elements of a claim must be found in one prior art source, a mere suggestion is not enough. Moreover, essential elements are not to be read into a reference. If a reference does not expressly recite or disclose Applicants' claimed invention, as is the case here, then, it is required under principles of inherency that the claimed subject matter be inevitably produced when the teachings of the relied upon reference are followed, in order for a proper case of anticipation to be found. For the reasons suggested above, it is believed that Applicants' claimed method is not fairly taught and that following the teachings of Reich et al. could not inevitably produce the invention, as claimed.

Accordingly, Reich et al. cannot be said to anticipate the present claims. In view thereof, it is respectfully requested that the grounds for rejection of applicants' claims 1 through 13 under 35 U.S.C. §102(b) as being anticipated by over Reich et al., be withdrawn.

The references cited by the Examiner as being of interest have been reviewed and found not to be pertinent to the issue of the patentability of the instant claims.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (14761).

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

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